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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,481	11/09/2006	Donald A. Tomalia	DNT-6 US	2400

50477 7590 06/25/2009

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EXAMINER	
BERNSHTEYN, MICHAEL	

ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
06/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,481	TOMALIA ET AL.	
	Examiner	Art Unit	
	MICHAEL M. BERNSHTEYN	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☒ Claim(s) *1-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-4 are objected to because of the following informalities: the claims recite the limitation "material", which has many different definitions (see paragraph 4 below). Therefore, in for chemical cases it would be better to use the words "ingredient", "reagent", "compound", etc.

Claim 2, line 2: recites "B2A" instead of B_2A.

Claim 3, line 1: the words "the method" after the word "polymers" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 recite the limitation "at room temperature in the range of about 0°C to about 200°C". Thus, claims 1-3 are indefinite for the following reason(s): in the claimed methods for preparing a monomer and hyperbranched, PAMAM polymers the temperature range is defined as 0-200°C, and at the same time the claims recite that the reaction is performed at room temperature. It is not clear which of the limitations governs the instant claims 1-3 because they contradict each other.

Specification

3. The abstract of the disclosure is objected to because it contains the spelling error in the word "itaconate".

4. A preliminary examination of this application reveals that it includes terminology which is so different from that which is generally accepted in the art to which this invention pertains that a proper search of the prior art cannot be made. For example: the specification and the claims 1-3 recite the limitation "material", which have a lot of different definitions, such as relating to, derived from, or consisting of matter; *especially* : PHYSICAL <the *material* world> (2): BODILY <*material* needs> **b** (1): of or relating to matter rather than form <*material* cause> (2): of or relating to the subject matter of reasoning; *especially* : EMPIRICAL <*material* knowledge>2: having real importance or great consequences <facts *material* to the investigation>3 a: being of a physical or worldly nature **b**: relating to or concerned with physical rather than spiritual or intellectual things <*material* progress> (see, for example, http://www.merriam-webster.com/dictionary/material)

Applicant is required to provide a clarification of these matters or correlation with art-accepted terminology so that a proper comparison with the prior art can be made. Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed). Correction is required. See MPEP § 608.01(b).

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 1-3 recite the limitation "at room temperature in the range of about 0°C to about 200°C for a period of time in the range of about 5 minutes to about 120 minutes: thereafter, adding solvent to the reaction mass and heating the mixture at less than 200°C for up to 24 hours" while the specification discloses that "The preparation of the AB_2 monomers is carried out at a temperature in the range of 0 to 10°C, with the preferred range being about 0 to 4°" (page 3, lines 23-24), and "The time for the polymerization reaction should be on the order of about one hour to about three days, and it is preferred that this range be on the order of about four hours to about 24 hours. Further, the range of temperature for carrying out this reaction should be on the order of about zero °C to about 150°C, and it is preferred for this invention that this range be about 40°C to about 100°C (page 3, line 30 through page 4, line 3).

Therefore, the limitation "at room temperature in the range of about 0°C to about 200°C" and "heating the mixture at less than 200°C" does not have support in the specification.

Claims 1-3 recites unlimited numbers of species, such as alkyl acrylates, aryl acrylates, alkyl methacrylates, aryl methacrylates, etc. which include many thousands of species, while the specification supports only three specie: methyl acrylate (Example 1, line 17), succinic anhydride, and dimethyl itaconate (abstract; Example 1, page 4, line 17; Example 2, page 5, line 29; Example 3, page 6, line 7). Therefore, all other species

except methyl acrylate, succinic anhydride, and dimethyl itaconate do not have support in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Migdal (U.S. Patent 4,938,885).

With regard to the limitations of claims 1, 2 and 4-6, Migdal discloses the product produced by first reacting an **alkyl acrylate** with an amine to produce an intermediate product, a first generation polyamine ester dendrimer which is then treated with an amine to produce a first generation polyamidoamine dendrimer which is then reacted with an **acrylate** to produce a second generation polyamidoamine ester dendrimer which with an amine is convened to a second generation polyamidoamine dendrimer which is then reacted with a polyisobutenyl **succinic acid anhydride** to produce the reactant product a polyisobutenyl succinimide-polyamidoamine dendrimer polymer (abstract, col. 2, lines 23-45). For specific reactions see reaction scheme in col. 3 and 4. Preparation of first generation polyamine ester dendrimer is discussed in Example 1 (col. 6, lines 33-49).

Methyl acrylate (284 g, 3.29 moles) was added to a two-liter, 3-nec.k flask equipped with mechanical stirrer, condenser, thermometer, and thermocouple. An addition funnel was charged with methanol (1 liter) and **tris-(2-aminoethyl)amine** (73 g, 0.50 moles). The contents of the addition funnel were added dropwise with stirring over 6 hours. The mixture was allowed to stand at room temperature for 48 hours at which point **excess methyl acrylate** and methanol were removed by vacuum distillation (4 mm Hg at 50 C.). This yielded 330 g for a 99% yield (Example 1, lines 33-49). Example 3 exemplifies the production of a second generation dendrimer (col. 7, lines 1-17).

With regard to the limitations of claim 3, Migdal discloses the use of **diethylene triamine** and its salts as an amine to react with **acrylate ester** (claim 6, col.13-14).

7. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Krause et al. (U.S. Patent 5,593,660).

Krause discloses iodine-containing dendrimeric polymers, agent containing these compounds, the use of these polymeric compounds as contrast medias well as processes for the production of these compounds and pharmaceutical compositions containing the same (abstract, col. 1, lines 6-10),

With regard to the limitations of claim 1, Krause discloses that 14.69 g (0.100 mol) of **tris-(2-aminoethyl)-amine**, dissolved in 20 ml of methanol, is instilled in 103.3 g (1.20 mol) of **methyl acrylate** with stirring at 20^0C. The batch is stirred under argon atmosphere for 5 days at room temperature and for 2 days at 50^0C. Then, it is concentrated by evaporation in a vacuum and **excess methyl acrylate** is removed by azeotropic distillation with toluene. The residue is taken up in 150 ml of methanol and

30 mi of diethyl ether, absorptively precipitated with 150 ml of hexane and, after separation of the hexane phase, concentrated by evaporation in a vacuum. The product is obtained as yellowish liquid, which is further reacted without purification (Example I(a), col.13, lines 30-46).

With regard to the limitations of claims 2, 4 and 5, Krause discloses different processes for making **dendrimers** of several generations, and the products which were prepared by these processes in (Examples I(b)-I(g), col. 13, line 47 through col. 14, line 39). It is noted that the described processes for preparing the monomer and hyperbranched, PAMAM polymers are substantially identical to the methods and the products of instant claims 1, 2, 4 and 5.

8. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Platzek et al. (U.S. Patent 6,299,859).

With regard to the limitations of claims 1 and 2, Platzek discloses a method for the preparation of monomers, wherein 7.6 ml of **tris(aminoethyl)amine** (50 mmol) is dissolved in 10 ml of methanol and added dropwise to 54.5 ml (600 mmol) of **methyl acrylate**. The mixture is stirred for 3 days at room temperature and then evaporated under vacuum. The remaining oil is precipitated from methanol/ether/hexane (Example 6(a), col. 36, lines 18-24).

With regard to the limitations of claims 4 and 5, Platzek discloses cascade or dendrimer polymers (Examples 6(b)-6(f), col. 36, line 30 through col. 37, line 38).

It is noted that the described processes for preparing the monomer and hyperbranched, PAMAM polymers are substantially identical to the methods and the products of instant claims 1, 2, 4 and 5.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL M. BERNSHTEYN whose telephone number is (571)272-2411. The examiner can normally be reached on M-Th 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1796

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